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| 08/873,597 | 06/12/1997 | JON FAIZ KAYYEM | A-64558-1/RF | 2066 |

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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 02/04/2003

46

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 08/873,597 | Applicant(s) KAYYEM, JON FAIZ | |
| | Examiner BJ Forman | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-31 and 33-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-31 and 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 11, 12, 13, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 12 April 2002 has been entered.

Claims 19-31 and 33-40 are pending.

Information Disclosure Statement

2. The references listed on the 1449 received 12 April 2002 have been reviewed and considered. A copy of the signed 1449 is enclosed with this action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19-25, 27-31 and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 19-21, 25, 30-31 and 33-34 are indefinite in Claim 19, step a), line 3 for the recitation "said electrode further comprise a passivation agent monolayer" because the recitation lacks proper antecedent basis in the claim. Therefore it is unclear whether the limitation modifies the first and/or second electrode. It is suggested that Claim 19 be amended to provide proper antecedent basis e.g. step a), line 3, insert "first" before "electrode".

b. Claims 19-21, 25, 30-31 and 33-34 are indefinite in Claim 19, step b), line 1 for the recitation "said first and second measuring electrode" because the recitation lacks proper antecedent basis in the first and second electrode of the claim. It is suggested that Claim 19 be amended to provide proper antecedent basis e.g. delete "measuring".

c. Claims 20-25, 30-31 and 33-34 are indefinite in Claim 20, step a), lines 2- 3 for the recitation "said electrode further comprise a passivation agent monolayer" because the recitation lacks proper antecedent basis in the claim. Therefore it is unclear whether the limitation modifies the first and/or second electrode. It is suggested that Claim 20 be amended to provide proper antecedent basis e.g. step a), line 3, insert "first" before "electrode".

d. Claim 21 is indefinite for the recitation "further comprising: d)" because the claim further limits Claims 19 and 20 which only recite components "a) and b)". Therefore, it is unclear whether there is an element missing from Claims 19 and 20. It is suggested that Claim 21 be amended to clarify e.g. delete "d)".

e. Claim 22 is indefinite for the recitation "said AC voltage source" because the recitation lacks proper antecedent basis in the AC/DC voltage source of Claim 19. It is suggested that Claim 22 be amended to provide proper antecedent basis e.g. replace "AC" with "AC/DC".

f. Claims 27-31 are indefinite in Claim 27, line 1 for the recitation "said single stranded nucleic acid" because the recitation lacks proper antecedent basis in Claim 26 which recites a "first single stranded nucleic acid". Therefore, it is unclear whether the recitation of Claim 27

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limits the first single stranded nucleic acid of Claim 26. It is suggested that Claim 26 be amended to provide proper antecedent basis e.g. insert "first" before "single".

g. Claims 27-31 are further indefinite in Claim 27, line 2 for the recitation "said electrode" because the recitation lacks proper antecedent basis in Claim 26 which recites a "first and second electrode". Therefore, it is unclear whether the recitation of Claim 27 limits the first and/or second electrode of Claim 26. It is suggested that Claim 26 be amended to provide proper antecedent basis e.g. insert "first" before "electrode".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 19, 21, 22, 35, 36, 39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al (U.S. Patent No. 5,849,486, filed 27 September 1996).

Regarding Claim 19, Heller et al disclose an apparatus for the detection of target nucleic acids comprising: a test chamber comprising a first and a second electrode wherein said first electrode comprises a single stranded nucleic acid covalently attached to said electrode via a spacer (Column 18, lines 18-42) wherein said electrode further comprises a

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passivation agent monolayer (i.e. permeation layer, Column 17, line 64-Column 18, line 35) and an AC/DC voltage source electrically connected to said first and second electrodes (Column 7, line 66-Column 8, line 16 and Column 19, lines 15-46).

Regarding Claim 21, Heller et al disclose the apparatus of Claim 19 further comprising a processor coupled to the electrodes (Column 6, line 46-Column 7, line 15).

Regarding Claim 22, Heller et al disclose the apparatus of Claim 19 wherein said AC voltage source is capable of delivering frequencies from between 1Hz to about 100 Hz (Column 19, lines 15-46 and Column 21, lines 31-49).

Regarding Claim 35, Heller et al disclose an apparatus for the detection of target nucleic acids comprising: a test chamber comprising an array of electrodes, each electrode comprising a covalently attached single stranded nucleic acid and a passivation agent monolayer (i.e. permeation layer, Column 17, line 64-Column 18, line 35) and an AC/DC voltage source electrically connected to said first and second electrodes (Column 7, line 66-Column 8, line 16 and Column 19, lines 15-46).

Regarding Claim 36, Heller et al disclose the apparatus of Claim 35 wherein at least one of said single stranded nucleic acids is covalently attached to said electrode via a spacer i.e. permeation layer (Column 18, lines 7-17).

Regarding Claim 39, Heller et al disclose the apparatus of Claim 35 wherein said passivation agent monolayer comprises conductive oligomers i.e. DNA probes attached to the surface (Column 18, lines 18-47).

Regarding Claim 40, Heller et al disclose the apparatus of Claim 35 wherein said passivation agent monolayer comprises insulators (Column 7, lines 50-65).

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7. Claims 19-31 and 33-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Kayyem et al (U.S. Patent No. 6,096,273, filed 5 November 1996).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 19, Kayyem et al disclose an apparatus for the detection of target nucleic acids comprising: a test chamber comprising a first and a second electrode wherein said first electrode comprises a single stranded nucleic acid covalently attached to said electrode via a spacer wherein said electrode further comprises a passivation agent monolayer (Column 23, lines 21-65) and an AC/DC voltage source electrically connected to said first and second electrodes (Column 37, lines 29-42).

Regarding Claim 20, Kayyem et al disclose an apparatus for the detection of target nucleic acids comprising: a test chamber comprising a first and a second electrode wherein said first electrode comprises a single stranded nucleic acid covalently attached to said electrode via a spacer wherein said electrode further comprises a passivation agent monolayer (Column 23, lines 21-65) and said nucleic acid further comprises a covalently attached first electron transfer moiety and an AC/DC voltage source electrically connected to said test chamber (Column 37, lines 29-42).

Regarding Claim 21, Kayyem et al disclose the apparatus of Claims 19 20 and 26 further comprising a processor coupled to the electrodes (Column 35, line 66-Column 36, line 47).

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Regarding Claim 22, Kayyem et al disclose the apparatus of Claims 19, 20 or 26 wherein said AC voltage source is capable of delivering frequencies from between 1Hz to about 100 Hz (Column 37, lines 29-42).

Regarding Claim 23, Kayyem et al disclose the apparatus of Claim 20 wherein said single stranded nucleic acid is covalently attached to said electrode via a spacer (Column 5, lines 23-55).

Regarding Claim 24, Kayyem et al disclose the apparatus of Claim 23 wherein said spacer is a conductive oligomer (Column 6, lines 35-38).

Regarding Claim 25, Kayyem et al disclose the apparatus of Claims 19, 23 or 27 wherein said spacer has the claimed formula (Column 6, line 35-Column 7, line 49).

Regarding Claim 26, Kayyem et al disclose an apparatus for the detection of target nucleic acids comprising: a test chamber comprising a first and a second electrode wherein said first electrode comprises a covalently attached first single stranded nucleic acid and passivation agent monolayer (Column 23, lines 21-65) and a second nucleic acid covalently attached to an electron transfer moiety (Column 25, line 65-Column 26, lines 45) and an AC/DC voltage source electrically connected to said test chamber (Column 37, lines 29-42).

Regarding Claim 27, Kayyem et al disclose the apparatus of Claim 26 wherein said single stranded nucleic acid is covalently attached to said electrode via a spacer (Column 5, lines 23-55).

Regarding Claim 28, Kayyem et al disclose the apparatus of Claim 27 wherein said spacer is a conductive oligomer (Column 6, lines 35-38).

Regarding Claim 29, Kayyem et al disclose the apparatus of Claim 27 wherein said spacer is an insulator (Column 23, line 55-Column line 42).

Regarding Claim 30, Kayyem et al disclose the apparatus of Claim 19, 23 or 27 wherein the spacer has the claimed formula (Column 3, lines 38-61).

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Regarding Claim 31, Kayyem et al disclose the apparatus of Claim 19, 23 or 27 wherein the spacer has the claimed formula (Column 12, line 65-Column 13, line 16).

Regarding Claim 33, Kayyem et al disclose the apparatus of Claims 19, 20 or 26 wherein said passivation agent monolayer comprises conductive oligomers (Column 23, lines 55-65).

Regarding Claim 34, Kayyem et al disclose the apparatus of Claim 27 wherein said passivation agent monolayer comprises an insulator (Column 23, line 55-65).

Regarding Claim 35, Kayyem et al disclose an apparatus for the detection of target nucleic acids comprising: a test chamber comprising an array of electrodes (Column 23, lines 22-34), each electrode comprising a covalently attached single stranded nucleic acid and a passivation agent monolayer (Column 23, lines 21-65) and an AC/DC voltage source electrically connected to said test chamber (Column 37, lines 29-42).

Regarding Claim 36, Kayyem et al disclose the apparatus of Claim 35 wherein at least one of said single stranded nucleic acids is covalently attached to said electrode via a spacer (Column 5, lines 23-55 and Column 23, lines 35-65).

Regarding Claim 37, Kayyem et al disclose the apparatus of Claim 36 wherein said spacer is an insulator (Column 23, lines 55-65).

Regarding Claim 38, Kayyem et al disclose the apparatus of Claim 36 wherein said spacer is a conductive oligomer (Column 23, lines 55-65).

Regarding Claim 39, Kayyem et al disclose the apparatus of Claim 35 wherein said passivation agent monolayer comprises conductive oligomers (Column 23, lines 55-65).

Regarding Claim 40, Kayyem et al disclose the apparatus of Claim 35 wherein said passivation agent monolayer comprises insulators (Column 23, lines 55-65).

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Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 19-31 and 33-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,096,273. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to electrodes having covalently attached single stranded nucleic acids and a passivation agent monolayer and differ only in the patent claims do not recite a first and second electrode and do not recite an AC/DC voltage source. However, the patent teaches that their composition comprises a first and a second electrode (array) (Column 23, lines 22-34) and includes an AC/DC voltage source (Column 37, lines 29-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the patent composition by adding a second and/or an array of electrodes and an AC/DC voltage source based on the teaching of the patent wherein the additional components are commonly utilized with the composition (Column 23, lines 22-34 and Column 37, lines 29-42).

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10. Claims 19-31 and 33-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-21 of U.S. Patent No. 6,248,229. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to similar apparatus comprising a test chamber comprising a first and second electrode comprising covalently attached ligands and passivation agent monolayer and an AC/DC voltage source.

The claims differ only in the patent claims are drawn to a generic binding ligand while the instant claims are drawn to species binding ligand i.e. single stranded nucleic acid. However, the patent teaches the preferred binding ligand is a single stranded (Column 4, lines 11-48). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the preferred binding ligand taught by the specification and to attach single stranded nucleic acids to the patent electrodes based on the patent teaching wherein the single stranded nucleic acid is a preferred binding ligand (Column 4, lines 11-48).

The claims further differ in the patent claims are drawn to a species passivation layer (i.e. those listed in step ii) while the instant claims are drawn to the genus passivation layer. The courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed genus passivation layer is obvious in view of the '229, passivation species.

Conclusion


11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
January 31, 2003